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(54) CARDIAC VALVE

(71) We, NATIONAL RESEARCH DEVELOPMENT CORPORATION, a British Corporation established by Statute, of Kingsgate House, 66—74 Victoria Street, Lcndon SW1E 6SL, do hereby declare the invention, for which we pray that a patent may be granted to us and the method by which it is to be performed, to be particularly described in and by the following statement:—

The natural atrio-ventricular valves in the human heart, that is the mitral valve in the left ventricle and the Tricuspid valve in the right ventricle act as non-return valves which control the blood flow from an atrium into a ventricle through an orifice in their dividing membrane, during the heart cycle. The natural valves comprise flexible cusps, effectively two in the case of the mitral valve and three in the case of the Tricuspid valve, which are attached to the periphery of the orifice and extend into the ventricle. Upon ventricular filling, blood is drawn from an atrium into a ventricle and the cusps of the valve move apart to open the valve and to allow the blood flow to take place. Upon ventricular contraction the cusps move together and close the valve.

Difficulties have existed in providing prosthetic atrio-ventricular valves particularly because the prosthetic valve must be implanted in the orifice in the thin wall dividing an atrium and a ventricle rather than in a duct as in the case of a prosthetic aortic valve. Accordingly a part of the prosthetic valve must project into at least one of the atria or ventricles and this disturbs the natural blood flow and promotes thrombosis.

Our research indicates that the atrio-ventricular valves have similar characteristics to the aortic and pulmonary valves in that when the valves are open the cusps provide a substantially cylindrical passageway for the blood permitting a laminar flow, the cusps being urged to their closed position by a ring vortex established within the ventricle and behind the cusps by the blood flow, together with a pressure difference tending to close the valve due to flow deceleration during the latter part of ventricular filling. The vortex persists when the blood flow decelerates so that the cusps approach their closed position before there is any appreciable backflow. The difference is that in the case of the aortic valve the vortices are set up in the sinuses in the wall of the aortic root. In the case of the atrio-ventricular valve the vortices formed behind the cusps in the ventricle appear to be produced by the flow of blood through the valve impinging on the far wall of the ventricle and being forced to flow back along the side walls of the ventricle.

The similar characteristics of the atrio-ventricular and aortic valves, for example in promoting laminar flow when open and in having cusps which are urged to a closed position by vortices produced by the flowing blood, has previously suggested to two of the present inventors that a prosthetic atrio-ventricular valve could be built on the model of the aortic valve, provided that the difficulties resulting from having to implant the valve in the orifice can be overcome. As a result Patent Specification No. 1,315,844 discloses a prosthetic valve, primarily for use as an atrio-ventricular valve, which is constructed on that model.

The valve disclosed in No. 1,315,844 has now beeen modified and improved by the present inventors and in accordance with the present invention a valve for use in a blood vessel comprises a tubular valve body formed by a love or a plurality of angularly spaced lobes each providing internally a hollow and externally a surface which is smoothly convex in both the circumferential and axial directions of the valve body, which has a maximum lateral protrusion between the axial ends of the valve body, and which at its end forming the upstream end of the valve body is curved so that a central portion of the or each lobe protrudes axially

beyond the remainder of the lobe and the valve body containing one or more thin flexible impermeable cusps, each one registering with the internal hollow provided by a respective lobe and each cusp being continuously sealed to the corresponding lobe along its upstream and axially extending edges but having a free downstream edge which terminates in the axial direction short of the downstream end of the corresponding lobe and which has a length such that when the valve is fully opened the or each cusp moves outwards towards its corresponding lobe to provide a passageway through the valve body for laminar flow but when the valve is closed the free downstream edge of the or each cusp moves inwards away from its lobe to obturate the valve opening, and the arrangement being such that the downstream part of the hollow provided by the or each lobe causes part of the flow through the valve to set up a vortex in the corresponding hollow tending to force the corresponding cusp inwards.

The new valve may be used in mechanical equipment for handling blood, for example in heart by-pass equipment such as is employed in cardiac surgery. However, the valve is primarily intended as a prosthetic atrio-ventricular valve for permanent cardiac implantation, in which case the valve body will be provided with a surrounding suture ring for sewing into the atrio-ventricular membrane. We also believe that the valve may have applications as a whole root replacement for the pulmonary valve in which case it may be provided with a suture ring at each end.

The valve may have one, two, three four or even more lobes and cusps, so that the upstream end of the valve body has a scallοped shape, and may be angularly symmetrical or asymmetrical. For example the mitral annulus is normally substantially elliptical in shape and there would be advantages in making the prosthetic valve body of substantially elliptical cross section with two major or one major and two minor lobes. In a unilobular valve, the downstream edge of the cusp will seal against the opposite wall of the valve body when the valve closes. In a multilobular valve the downstream edges of the cusps will close against one another along radial planes.

Since the valve is to be used without anticoagulant therapy, it is necessary to avoid turbulant flow and stagnant regions which both contribute to thrombosis. The cusp or cusps open to allow laminar flow but move inwards to interrupt the flow under the vortex action upon deceleration of the flow, as with the valve of No. 1,315,844. The external convex shape of the tubular body has the advantage, also in common with the valve described in No. 1,315,844 that, when the valve is used as a prosthetic atrio-ventricular valve, the stubby externally convex projections which extend on one or both sides of the atrio-ventricular membrane into the atrium and/or ventricle are swept by the blood flow and provide the minimum obstruction where thrombosis might occur. This danger is reduced even further by the curved upstream ends of the lobes which, particularly in multilobular valve forms, give the upstream end of the valve body a scalloped effect, as the blood can flow around or between the upstream end or ends of the lobe or lobes. The length of the valve body is also effectively reduced at the sides of the lobe or between the lobes with a consequent advantage of providing prosthetic valves with larger effective orifices, whilst retaining the advantages of laminar flow.

The valve body should be shape-sustaining and provide a secure mounting for the cusps without being so hard that it irritates the adjacent parts of the heart as they move naturally. Preferably the valve body is made from a woven or knitted textile fabric such as knitted polyethylene terephthalate which may be coated with a suitable rubber such as a silicone or segmented polyurethane rubber. Two or more layers of the fabric bonded together with the rubber may be used to sandwich the edges of the cusps and so provide a strong and smooth attachment for the cusps. This produces a resilient body which has a certain ability to move with the heart, but has no rigid skeleton.

The suture rings may be made from a woven or knitted textile fabric, such as a fine uncut polyethylene, terephthalate velour which provides a surface into which natural tissue will grow and readily knit.

The cusps may be made from a rubber such as a silicone or segmented polyurethane rubber, which may or may not be reinforced with a fabric. Where fabric reinforcement is used, this may be a knitted 11 denier polyethylene terephthalate fabric.

In the valve of No. 1,315,844 the lobes and cusps were connected at an inwardly projecting seam. We now believe that these seams themselves provide potential areas for thrombosis formation. In the new valve when the edges of the cusps and lobes are smoothly laminated together, no internally or externally protruding seam is formed. Preferably at least the external ply of adjacent lobes are continuous with one another.

One example of a tricuspid prosthetic mitral valve constructed in accordance with the present invention is illustrated in the accompanying drawings, in which:—

Figure 1 is a downstream end elevation;

Figure 2 is an upstream end elevation;

Figure 3 is a section taken on the line III—III in Figure 1;

Figure 4 is a section taken on the line IV—IV in Figure 2;

Figure 5 is a perspective view partly broken away in section; and,

Figure 6 is a diagrammatic view showing the prosthetic valve implanted in the heart.

The valve comprises a tubular body formed by three similar lobes 7 each of which provides internally a hollow 8 and externally a smoothly convex surface which has a maximum lateral projection at 9 between the axial ends of the body. In the orientation of Figure 3, the direction of flow through the valve body is upwards. At the upstream end of the body each lobe has a curved periphery so that the central portion 11 of each lobe protrudes axially beyond the remainder of the lobe at the upstream end of the valve body and particularly beyond points 10 where adjacent lobes meet. This gives the upstream end of the valve a scalloped shape.

The valve body is a laminate formed from inner and outer plies of fine knitted polyethylene terephthalate (of the kind sold under the trade mark "Terylene") with a layer of silicone rubber sandwiched between and bonded to the plies. The external fabric ply is continuous throughout the whole periphery of the valve body. The tubular body thus formed is shape-sustaining but with some resilient flexibility and produces an oblate barrel shaped body with three lobes 7 providing internal hollows 8 which are analogous to the sinuses in a natural aortic valve.

Three cusps 12, made of silicone rubber reinforced with a knitted 11 denier polyethylene terephthalate (of the kind sold under the trade mark "Terylene") fabric are mounted within the tubular body, one cooperating with each hollow 8. Each cusp has a curved edge corresponding in shape to the curve at the upstream end of each lobe and this curved edge of the cusp is lapped inside the inner ply of the laminate forming the lobe to form a smooth seal between the curved edge of the cusp and the corresponding curved edge of the lobe. The free edge of each cusp is a substantially straight edge 13 which terminates short of the downstream end of the tubular body.

When blood flows through the valve the cusps 12 open to the position shown in Figure 3, and so that the free edges 13 of the cusps adopt the positions 13' shown also in Figures 1, 2, and 5. In this configuration the cusps surround a substantially cylindrical passageway allowing laminar flow through the valve. However, the free edges 13 of the cusps are spaced from the valve body by a small gap 14. As a result, and in an analogous manner to that occuring in the aortic valve, the blood flow through the valve sets up vortices within the hollows 8 behind the cusps 12, these vortices tending to urge the cusps radially inwards. As soon as the flow deccelerates therefore the cusps move inwardly until their free edges 13 abut one another along equiangularly spaced radial planes of contact as shown in Figures 1, 2, 4, and 5, thus closing the valve and preventing backflow.

As shown in Figure 6, the prosthetic mitral valve will be secured in the mitral opening 16 between an atrium and the left ventricle 17. The aortic root is shown at 18. The valve is located by means of a suture ring 19 which is made of fine uncut polyethylene terephthalate (of the kind sold under the trade mark "Terylene") velour which is stitched to the outside of and surrounds the tubular body. When the valve is implanted the ring 19 is sewn to the mitral opening. We find that the velour is extremely acceptable to the natural tissue which readily grows into and knits with the velour.

The axial position at which the suture ring 19 is sewn to the valve body depends upon the extent to which the convex valve body is required by the surgeon to project into the left ventricle or into an atrium.

WHAT WE CLAIM IS:—

1. A valve for use in a blood vessel, the valve comprising a tubular valve body formed by a lobe or a plurality of angularly spaced lobes each providing internally a hollow and externally a surface which is smoothly convex in both the circumferential and axial directions of the valve body, which has a maximum lateral protrusion between the axial ends of the valve body, and which at its end forming the upstream end of the valve body is curved so that a central portion of the or each lobe protrudes axially beyond the remainder of the lobe and the valve body containing one or more thin flexible impermeable cusps, each one registering with the internal hollow provided by a respective lobe and each cusp being continuously sealed to the corresponding lobe along its upstream and axially extending edges but having a free downstream edge which terminates in the axial direction short of the down-stream end of the corresponding lobe and which has a length such that when the valve is fully opened the or each cusp moves outwards towards its corresponding lobe to provide a passageway through the valve body for laminar flow but when the valve is closed the free downstream edge of the or each cusp moves inwards away from its lobe to obturate the valve opening, and the arrangement being such that the downstream part of the hollow provided by the or each lobe causes part of

the flow through the valve to set up a vortex in the corresponding hollow tending to force the corresponding cusp inwards.

2. A valve according to claim 1, in which there are two or more lobes, so that the upstream end of the valve body has a scalloped shape, and, when the valve is closed, the free downstream edges of the cusps meet and seal against those of the adjacent cusp or cusps along radial planes to obturate the valve opening.

3. A valve according to claim 2, in which there are three substantially equi-angularly spaced lobes.

4. A valve according to any one of the preceding claims, in which the valve body is made from a woven or knitted textile fabric.

5. A valve according to claim 4, in which the textile fabric is made from polyethylene terephthalate.

6. A valve according to claim 4 or claim 5, in which the fabric is coated with a silicone or segmented polyurethane rubber.

7. A valve according to claim 6, in which the valve body is formed as a laminate from at least two layers of the textile fabric with a layer of the rubber snadwiched between them.

8. A valve according to claim 7, in which the edges of the cusps are laminated with the valve body to provide a structure with no internally or externally protruding seams.

9. A valve according to any one of the preceding claims in which the cusps are made from a silicone or segmented polyurethane rubber.

10. A valve according to claim 9, in which the cusps are reinforced with a fabric reinforcement.

11. A valve according to claim 10, in which the fabric reinforcement is a knitted 11 denier polyethylene terephthalate fabric.

12. A prosthetic valve according to any one of the preceding claims for permanent cardiac implantation, in which at least one suture ring is secured to the outside of and extends around the tubular body.

13. A valve according to claim 12, in which the or each suture ring is made of a woven or knitted textile fabric.

14. A valve according to claim 13, in which the woven or knitted textile fabric is a fine uncut polyethylene terephthalate velour.

15. A valve according to claim 1, substantially as described with reference to the accompanying drawings.

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1477643 COMPLETE SPECIFICATION

2 SHEETS *This drawing is a reproduction of the Original on a reduced scale*

Sheet 1

Fig.1.

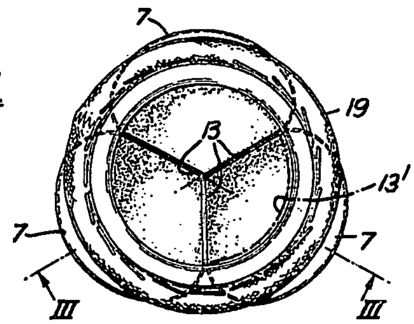


Fig.2.

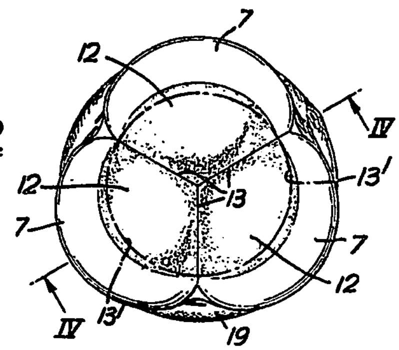
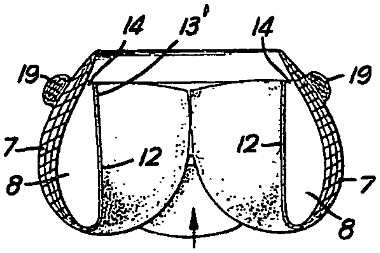


Fig.3.



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Sheet 2

Fig.4.

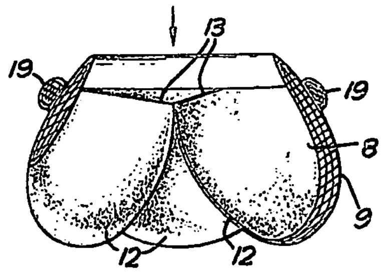

Fig.5.

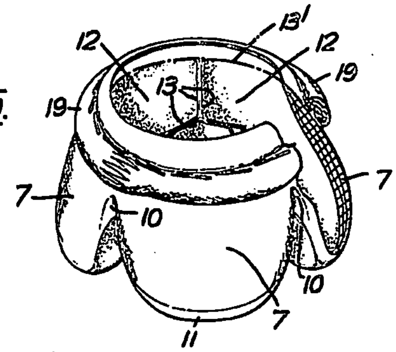

Fig.6.